

Appl. No. : 09/912,472
Filed : July 24, 2001

SUMMARY OF INTERVIEW

The undersigned wishes to thank Examiner Cook for the courtesy extended to him during a telephonic interview on October 11, 2005. During that conversation between the undersigned and Examiner Cook, the three issues raised in the final Office Action were discussed, and the undersigned proposed to address them as follows: (1) The indefiniteness rejection would be addressed by amending Claims 11 and 12 so that the preamble provides antecedent basis for the phrase "reducing blood glucose levels." Support is found throughout the specification, e.g., Column 2, lines 57-65. (2) The double patenting rejection would be addressed by submitting a terminal disclaimer. (3) The § 103(a) rejection will be addressed by pointing out data in the Komorowski declaration comparing the use of biotin alone and chromium alone with the results obtained from the combination of the two.

Examiner Cook agreed to reconsider the rejection under 35 U.S.C. § 103(a) in view of these proposed changes and remarks.

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REMARKS

Claims 1-26 are pending in the present application.

Applicant has amended Claims 11 and 12 to replace the phrase "reducing hyperglycemia" with the phrase "reducing blood glucose levels." Applicants maintain that the amendments add no new matter and are fully supported by the specification as originally filed. Support for the phrase "reducing blood glucose levels" can be found, for example, in Column 2, lines 57-65.

Claims 1-26 are presented for examination. Applicant responds below to the specific rejections raised by the Examiner in the final Office Action mailed September 14, 2005. For the reasons set forth below, Applicant respectfully traverses.

Rejection Under 35 U.S.C. § 112, second paragraph

The Examiner has rejected Claims 11-26 as indefinite. Specifically, the Examiner argues that the phrase "in reducing blood glucose levels" lacks antecedent basis. Claims 11 and 12 have been amended to replace the phrase "reducing hyperglycemia" with the phrase "reducing blood glucose levels." As amended, the recitation of "reducing blood glucose levels" in the preamble of Claims 11 and 12 now provides antecedent basis for the phrase "reducing blood glucose levels" in the body of the claims. Accordingly, Applicant requests that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 112, second paragraph.

Rejection Under 35 U.S.C. § 103(a)

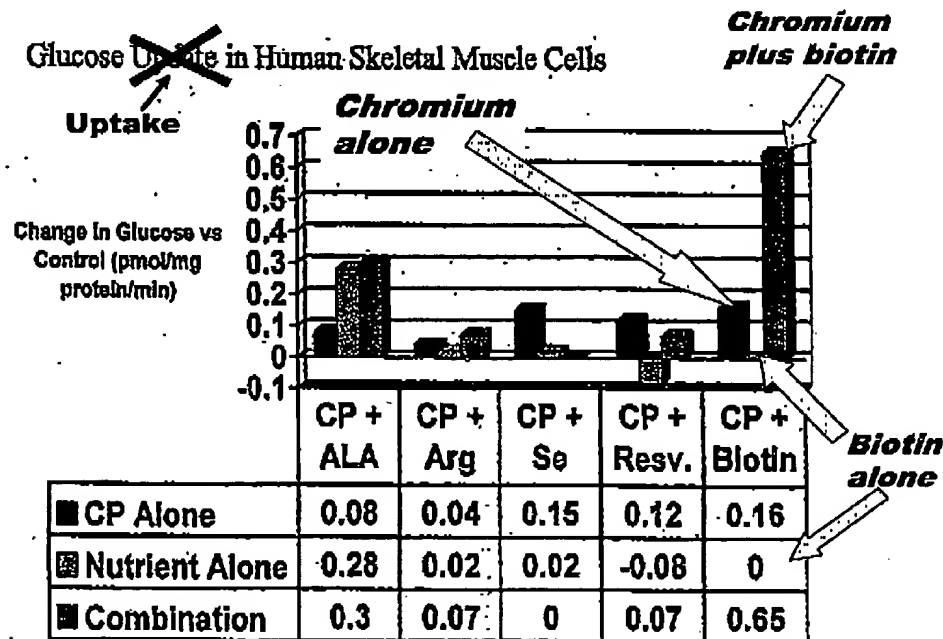
The Examiner has maintained the rejection of Claims 10 and 25 as allegedly being unpatentably obvious over U.S. Patent 5,635,535 ("Wagstaff") for the reasons set forth in the Office Action mailed November 12, 2004. The Examiner has also maintained the rejection of Claims 1-26 as allegedly being unpatentably obvious over Anderson and Maebashi *et al.* for the reasons set forth in the Office Action mailed November 12, 2004, i.e., that the individual ingredients (chromium and biotin) would each be expected to have activity; thus, their combination produces an expected result.

In the previous response to these rejections, Applicant submitted a Second Declaration of James Komorowski under 37 C.F.R. § 1.132, accompanied by experimental data presented in Exhibit C. It is believed that the Second Declaration and Exhibit C overcome the Examiner's

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rejection under 35 U.S.C. § 103(a) by demonstrating synergistic effects of chromium and biotin combinations on lowering blood glucose levels.

Based on the Final Office Action and the interviews, it is believed that the only remaining obstacle to overcoming the obviousness rejection is the question of whether the data show results for biotin alone, as well as data for chromium alone, supporting the conclusion that the combination of the two gives synergistic results. Such data are present in Exhibit C to the Second Declaration. Applicants apologize that those data were not readily apparent from the Figure. The relevant portion of Exhibit C (Figure 1) from that Declaration is reproduced below, with the requested information identified:



Thus, this figure shows that chromium picolinate alone caused an increase in glucose uptake of 0.16, biotin alone had almost no effect, and the chromium + biotin combination caused an unexpected increase of 0.65 pmol/mg protein/min. See, e.g., Second Komorowski Declaration, Para. 9.

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Further, the Examiner inquired why Exhibit C (Figure 1), included data for glucose uptake with combinations of chromium and ALA, Arg, Se, and Resv. The inclusion of the ALA, AArg, Se, and Resv. data in Exhibit C is due to the fact that the experiments with chromium and biotin were part of a larger study, measuring the effects of other nutrients alone and in combination with chromium, on glucose uptake. These data emphasize the unexpected nature of the chromium/biotin results. The inclusion of these compositions is believed to be informational only, and not necessary for overcoming the prior art rejection.

(Applicant notes a typographical error in Exhibit C, where "Update" should have been "Uptake." This correction is noted -on the annotated ~~[?]~~ figure above, but since the intent is clear, a revised declaration is not believed necessary.)

In view of the objective evidence submitted in Exhibit C, as well as the testimony of James Komorowski (Second Declaration Under 37 C.F.R. § 1.131), Applicant submits that the combination of chromium and biotin would not have been obvious in view of either U.S. Patent 5,635,535, or in view of Anderson in further view of Maebashi *et al.* Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of Claims 1-26 under 35 U.S.C. § 103(a).

Non-statutory Double Patenting Rejection

The Examiner has rejected Claims 1-26 under the judicially created doctrine of obviousness-type double patenting over Claims 1-10 of U.S. Patent No. 5,789,401 for the reasons set forth in the Office Action mailed November 12, 2004. The Examiner suggests a terminal disclaimer.

Applicant submits herewith a terminal disclaimer, and accordingly requests that the Examiner reconsider and withdraw the rejection of Claims 1-26 above.

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BEST AVAILABLE COPY**CONCLUSION**

In view of the above, Applicant respectfully maintains that the claims are patentable and request that they be passed to issue. Applicant invites the Examiner to call the undersigned if any remaining issues may be resolved by telephone.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 10-14-05

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